Mary Ann Olteanu Box 338 Wilmington, Vermont 05363

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April 26, 1999

Dockets Management Branch (HFA-305) FDA- Docket No. 98N-1265 Food and Drug Administration 5600 Fishers Lane Rockville, MD 208 57

Ladies and Gentlemen:

I strenuously oppose the Draft Memorandum being proposed by the FDA. In particular, I object to the definition of "inordinate amount" which restricts the availability and the right to obtain medically necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

First of all, I would like to know WHY this was proposed, as I can see no reason why such shipments should be restricted from a legally licensed pharmacy. What difference could it possibly make that the destination is out-of-state?

Secondly, I regularly get a prescription filled from an out-of-state formulary pharmacy because my prescription is for natural, HUMAN estrogen, which is not a brand-name, highly profitable, patented formula. All I can get here is expensive, patented estrogen made from horse urine, which causes me a number of very unpleasant side effects. As a post-menopausal woman who is at very high hereditary risk for heart attack, it is essential that I continue to take estrogen without suffering impossible side effects.

This smacks of heavy influence from large, mass-market pharmaceutical houses who wish to limit my medication choices to those that most profit them. I also suspect that they are alarmed by the competition from internet drug outlets, which is probably the REAL reason behind this! HOW CAN YOU POSSIBLY JUSTIFY THIS PROPOSAL???! You must abandon this highly irrational and suspect intrusion into choices that are between me and my doctor. Butt out!

Sincerely yours,

Mary Ann Olteanu

Copy to: State of Vermont Pharmacy Board.

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